IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DEBRA ACREE, as Independent Administrator of the Estate of WILLIAM ACREE, JR., deceased,	)	
Plaintiff,	)	
vs.	)	**Case No. 10 C 7812**
WATSON PHARMACEUTICALS, INC., et al.,	)	
Defendants.	)	

ORDER REGARDING DEFENDANTS' MOTIONS IN LIMINE

MATTHEW F. KENNELLY, District Judge:

In this order, the Court rules on defendants' motions *in limine*.

A. Comparison of Watson's patch design with "matrix" design (motion 4)

The Court denies defendants' request to bar evidence relating to alternative designs for fentanyl patches, including evidence relating to "matrix"-type patches. Defendants contend that plaintiff has made no claim of a design defect that is distinct from her other claims. This is incorrect. Plaintiff has asserted claims of strict product liability design defect and negligent design. The evidence supporting these contentions overlaps with the evidence supporting plaintiff's contention that there was a manufacturing defect, but this is not a basis for precluding evidence to support the design-based claims.

The evidence is plainly relevant and admissible. Nor is it *unfairly* prejudicial in a way that substantially outweighs its probative value. *See* Fed. R. Evid. 403.

Defendants' argument to the contrary essentially asks the Court to weigh all of the other evidence favorably to defendants and then use that as a predicate to preclude the alternative-design evidence. Defendants cite no case supporting that approach, which is fundamentally inconsistent with how Rule 403 is supposed to work. Evidence-weighing is a function for the jury, not the Court, and the Court has already ruled in denying summary judgment that plaintiff has offered sufficient circumstantial evidence to permit a jury to find in her favor.

B. Evidence of "products under development" (motion 7)

Defendants ask the Court to bar evidence regarding their development of an alternative patch design – again, a matrix patch. They contend this is irrelevant on the question of whether defendants' design was defective. Plaintiff notes in response that in a report regarding the alternative design, prepared in late 2008 (a time relevant to plaintiff's claims), a Watson representative stated that the company had decided to design a matrix patch because it would be "easier to process and manufacture than liquid reservoir style system [sic] and won't exhibit some of the critical defects associated with liquid reservoir systems such as inadequate reservoir seals and the leaking of fentanyl gel from the reservoir." Pl.'s Resp. to Defs.' Mots. In Limine, Ex. 69. This evidence is unquestionably relevant and properly admissible on the issues of defect and notice, as well as on the question of "the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility," a relevant consideration in a design defect case. *Jablonski v. Ford Motor Co.*, ___ Ill. 2d___, 955 N.E.2d 1138, 1154 (2011). The Court denies defendants' motion.

C. Bobrowicz report (motion 8)

Defendants have moved to exclude a July 2008 report prepared by Greg Bobrowicz, a consultant defendants hired to review their fentanyl patch manufacturing process in preparation for an inspection by the Food and Drug Administration. The report describes, among other things, deficiencies in defendants' process.

Defendants' objection that the FDA did not make any adverse findings following its inspection has no bearing on the admissibility of the report. Rather, this affects (if anything) only the report's weight.

Defendants contend that the report is inadmissible hearsay. Even if it were hearsay, the report – at least the parts of it that concern problems in defendants' manufacturing process – would be admissible to show that the defendants were on notice of these issues. Contrary to defendants' argument at the motion hearing, evidence that defendants were told at a relevant time that there was something wrong (or more than one thing wrong) with their patch manufacturing process is unquestionably relevant on the question of whether they exercised reasonable care.

In any event, the report is not hearsay. The evidence reflects that defendants hired Bobrowicz to review their patch manufacturing process and gave him access to their facilities, employees, and records. Defendants then distributed the report to Watson personnel who used it to prepare for the FDA inspection. These factors are sufficient to make Bobrowicz's report admissible as non-hearsay under Federal Rule of Evidence 801(d)(2)(D). *See, e.g., Reid Bros. Logging Co. v. Ketchikan Pulp Co.*, 699 F.2d 1292, 1306-07 (9th Cir. 1983).

Defendants argue that the report is irrelevant because it does not deal with the

particular patch that Mr. Acree was using when he died or the lot from which that patch came. This is a roundabout way of suggesting that only direct evidence is admissible. That is not the case. Evidence that at times prior to Mr. Acree's death defendants had (and were aware that they had) a manufacturing process that arguably was replete with flaws that led to defective patches and that defendants had inadequate quality control is relevant even if his report does not concern the particular patch or lot at issue in this case. As plaintiff notes, the report concerned the same manufacturing plant and the same equipment and process used to manufacture the patches that Mr. Acree was wearing. The report (or at least parts of it) is relevant, and for the same reason it has significant probative value that is not substantially outweighed by any claimed unfair prejudice defendants would experience from its admission.

It is unlikely, however, that the entire report is relevant, at least for purposes of plaintiff's case in chief. The material in the report regarding leakages, other failures in the manufacturing process, and problems with quality control is relevant and admissible with regard to (if nothing else) the questions of negligence and notice, even if it does not concern leakages in particular. A good deal of the rest of the 21-page report may be sufficiently tangential or confusing in a way that might render those portions subject to exclusion under Federal Rule of Evidence 403. The Court directs plaintiff to be prepared to show, at an appropriate point at or near the outset of the trial, which portions of the report she proposes to introduce in its case in chief so that the Court can hear from defendants and make a determination. (The Court notes that if defendants offer testimony by their manufacturing process expert in their case, there is a good chance that the entire Bobrowicz report will be admissible in rebuttal.)

D. Opinions of Michael Anisfeld (motion 11)

Defendants have moved to exclude the opinions of Michael Anisfeld. They target his opinions that defendants' manufacturing process did not comply with the FDA's "good manufacturing processes" and that defendants should have stopped manufacturing fentanyl patches. Defendants also challenge Anisfeld's opinion that there is no guarantee that Watson's patches were not defective and that it is possible that Mr. Acree received a patch that was defective.

Defendants' contention that Anisfeld's opinion that defendants should have stopped manufacturing fentanyl patches due to problems runs afoul of Congress's conferral upon the FDA of the sole authority to stop the sale of a pharmaceutical product and to enforce the provisions of the Food, Drug, and Cosmetic Act are entirely lacking in merit. Plaintiff is not asserting a claim for violation of federal law or any sort of claim that is preempted by federal law. Anisfeld's opinions regarding defendants' manufacturing process are relevant and admissible on, among other things, the question of negligence.

The Court has a different view, however, regarding the admissibility of Anisfeld's opinion that is phrased in terms of "possibility." Neither side provided the Court with a copy of Anisfeld's Rule 26(a)(2) report or his deposition testimony in connection with the motions *in limine*. The Court reviewed the docket and found what appears to be Anisfeld's report as part of plaintiff's summary judgment materials. *See* Pl.'s Resp. to Defs.' Mot. for Summ. Judg., Ex T. The part of the report addressing this point is at the end and reads as follows:

Opinion Number Nine:

There is a chance that any person who has ever purchased or used an FTS, including William Acree, received an FTS that was defectively manufactured and Watson is wholly unable to say William Acree did not receive a defective leaking FTS.

Rationale for Opinion Number Nine:

89. Watson admits that even with all of the policies, processes and equipment they used to produce reservoir fentanyl patches today, they simply cannot guarantee that a patient will not receive a defective leaking patch:

> Q. If a person were to say that they had bought a Watson reservoir fentanyl patch at any period of time from 2007 all the way up through 2011, you certainly know it's possible they got a defectively manufactured leaking patch. Right?
>
> A. There have been leaking patches returned from the field.
>
> Q. It is accurate to say that for any time period from 2007, 2008, 2009, 2010 even 2011 Watson cannot rule out the fact that it's impossible that a person got a defectively manufactured leaking patch. Correct?
>
> A. We cannot rule out, it is impossible.
>
> (Deposition of Charles Ebert Pages 292:2 – 293:4.)

90. In my opinion, any person who has ever purchased or used an FTS has a chance that the FTS they received was defectively manufactured and could leak fentanyl gel and Watson cannot unequivocally state any particular FTS that was received by a patient was a not a defective leaking, potentially deadly, FTS.

Id. ¶¶ 89-90 (bold type in original).

The Court excludes this aspect of Anisfeld's opinion. The reference that he makes in paragraph 89 of his report simply repeats testimony that can otherwise be admitted into evidence directly; no expert is needed to communicate this to the jury. The opinion that Anisfeld renders in paragraph 90 simply paraphrases that same testimony in a more argumentative way. Again, no expert is needed to make this

argument to the jury.

E. Dr. Downs & Dr. Prausnitz

Defendants have moved to preclude the testimony of defense expert Dr. J.C. Upshaw Downs, a forensic pathologist, and Dr. Mark Prausnitz, a chemical and biomedical engineer and an expert in transdermal drug delivery.

The admission of expert witness testimony is governed by Federal Rule of Evidence 702 and the principles set forth by the Supreme Court in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). Specifically, a court "must determine whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue." *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010) (internal quotation marks omitted). The court serves a "gatekeeping" function to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. As such, the court does not decide whether the expert's views are correct but instead "is limited to determining whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound." *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000).

1. Dr. Downs

Plaintiff intends to elicit from Dr. Downs an opinion that Mr. Acree died from a fentanyl overdose. He bases this on the fact that Mr. Acree's postmortem blood fentanyl level of 23.6 nanograms per milliliter was significantly greater than the amount of fentanyl his patches were supposed to deliver and was within the reported lethal

range and that this was the only substance detected in his blood that was significantly elevated.

Defendants contend that the proposition that one can determine or estimate a person's antemortem fentanyl level from his postmortem fentanyl level is refuted by scientific studies. There is, however, scientific literature that supports the proposition that postmortem redistribution (PMR) of fentanyl is minimal. The Court acknowledges, as defendants note, that there are studies that show otherwise, but it is not the function of the Court to determine which view is more persuasive. As another court has stated, "[t]he role of the Court when ruling on a *Daubert* motion is not to resolve the scientific debate, but to determine whether plaintiffs' experts have a reliable basis for their testimony." *Palmer v. Asarco, Inc.*, 510 F. Supp. 2d 519, 527 (N.D. Okla. 2007). Plaintiff has adequately shown this.

Defendants also challenge Dr. Downs' use of what they contend is an unsupported central-to-peripheral ratio ("C/P ratio") to estimate the amount of PMR that might have occurred. Without getting into the details of the analysis, Dr. Downs' opinion includes a statement that even if PMR had occurred, the effect would be clinically insignificant. *See* Pl.'s Resp. to Defs.' Mots. In Limine, Ex. 1 ¶ 11. This conclusion is partially based on a C/P ratio that defendants argue is without a scientific basis, largely because it varies from certain averages and means reported in the literature. The Court concludes that Dr. Downs' opinion, including the C/P ratio he references, is supported by scientific study such that it is properly admissible. Defendants' arguments about this and other aspects of Dr. Downs' analysis may be good points for cross-examination and may affect the weight to be given to his testimony, but they do not render it

inadmissible. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

In sum, the Court is persuaded that Dr. Downs' testimony does not amount to *ipse dixit* unconnected to the underlying data. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). The Court denies defendants' motion *in limine*.

2. Dr. Prausnitz

Defendants argue that Dr. Prausnitz: (1) bases his opinion on an unsupported assumption that Mr. Acree's postmortem blood fentanyl level was unaffected by PMR and thus is equivalent to his antemortem level; (2) premises his opinion on an unsupported hypothesis that if fentanyl gel leaks onto one's skin, a large amount of it will be absorbed through the skin and pass into the blood stream; and (3) adopts that hypothesis even though he has done no studies to support it and in the absence of evidence of a leak in Mr. Acree's fentanyl patches.

The basic problem with defendants' argument is that they effectively ask the Court to disregard or discount evidence supporting plaintiffs' contentions on these points. Weighing and assessing that evidence is the function of a jury, not the Court. In any event, there *is* evidence to support each of the purported assumptions that defendants attack. The medical examiner who conducted the autopsy on Mr. Acree concluded that that fentanyl intoxication was the cause of his death; there is evidence that defendants' fentanyl patches have leaked, although the particular patches that Mr. Acree used were discarded; defendants themselves have issued warnings (in a way that a reasonable jury could find is actually attributable to them) that leakage from a

patch can cause a fatal dosage of fentanyl; published studies support the proposition that the delivery rate of fentanyl increases if the substance comes into direct contact with the skin; and there are scientific studies and other evidence that supports the proposition that PMR did not significantly impact Mr. Acree's blood fentanyl level.

There is, to be sure, contrary evidence on each of these points, but that does not affect the admissibility of Dr. Prausnitz's testimony. *See Smith*, 215 F.3d at 718 ("The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact"). An expert's testimony cannot be based on speculation or subjective opinion, *see, e.g., Metavente Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 761 (7th Cir. 2010), but Dr. Prausnitz's opinions are not based on speculation. And there is nothing inappropriate about Dr. Prausnitz's reliance on Dr. Downs' opinions. An expert may rely on the opinions or data of others unless the underlying basis is faulty or the testifying expert's opinion is speculative, *see, e.g., NutraSweet Co. v. X-L Eng'g Co.*, 227 F.3d 776, 789-90 (7th Cir. 2000), and neither is the case with regard to Dr. Downs.

Defendants also take issue with Dr. Prausnitz's opinion that a leaking fentanyl patch is the most probable explanation of the elevated level of fentanyl in Mr. Acree's blood. They characterize Dr. Prausnitz's testimony as reaching this conclusion by ruling out other possible explanations after concluding that there is no evidence to support any of them. There is nothing logically or scientifically inappropriate about this sort of analysis. Defendants argue that Dr. Prausnitz's analysis is flawed because the same could be said of his opinion that a fentanyl overdose was the cause of death (i.e., that there is no evidence to support it). Defendants are, quite simply, wrong about this. The

Court need not catalog again the evidence that supports plaintiffs' contention and Dr. Prausnitz's opinion that a fentanyl overdose caused Mr. Acree's death, other than to say that it is more than sufficient to support his opinion. The fact that there may be no *direct* evidence is of no consequence. As the Court noted in its summary judgment ruling, Illinois law, which applies here, quite clearly allows a plaintiff to prove a case of this sort via circumstantial evidence.

For these reasons, the Court denies defendants' motion to bar Dr. Prausnitz from testifying.

F. AIT blood test report; use of postmortem fentanyl level (motions 1 & 2)

The Court denies defendants' motions to bar evidence of Mr. Acree's postmortem blood fentanyl level and opinions that this can be used to estimate the antemortem blood level for the reasons discussed above.

G. Evidence / argument that a patch leak can be inferred (motion 6)

Defendants ask the Court to preclude any evidence or argument that a fentanyl patch leak can be inferred from other evidence. Their motion states that the grounds for this request "are the same as those set forth in the *Daubert* Motion [to bar plaintiff's experts], as well as Defendants' request to exclude the opinions of Plaintiff's expert Michael Anisfeld." Defs.' Mot. In Limine at 6. The Court denies this motion for the reasons stated with regard to those motions.

H. Evidence regarding other incidents (motions 3, 5, 9 & 10)

Defendants have moved to bar evidence of recalls of certain fentanyl patch lots; evidence of other incidents in which their fentanyl patches leaked; "health hazard evaluation" reports they prepared internally; and evidence concerning "adverse event

reports" received from physicians and others regarding leaking fentanyl patches. The Court addresses these motions together because they address overlapping subjects.

Evidence of other accidents or incidents is relevant in a product liability case "to show notice to the defendant of the danger, to show existence of the danger, and to show the cause of the accident." *Nachtsheim v. Beech Aircraft Corp.*, 847 F.2d 1261, 1268 (7th Cir. 1988). The proponent must show that the other incidents occurred under substantially similar circumstances. *Id.* The requirement of similarity "is less strict" when the evidence is sought to be admitted to show notice. *Id.* at 1268 n.9. In *Nachtsheim*, the Seventh Circuit cited with approval a case that it said stood for the proposition that "for purposes of showing notice, previous injury need only be such as to attract the defendant's attention to the dangerous situation." *Id.* (citing *Elsworth v. Beech Aircraft Corp.*, 37 Cal. 3d 540, 555, 691 P.2d 630, 639 (1984) (en banc)).

If the other incident meets the similarity standard, the fact that it occurred after the incident at issue in the lawsuit does not render it inadmissible with regard to issues of danger and causation. "While only earlier accidents can be relevant to the issue of notice, causation is an issue affected only by the circumstances and the equipment, and is not related to the date of the occurrence." Id. at 1268 n.8 (internal quotation marks omitted).

The Court begins with the "recall" evidence. The two recalls at issue both involved leaking patches, the same sort of defect that plaintiff alleges in this case. As defendants point out, they involved different lots than the patches that Mr. Acree wore, and one of them involved patches of a different dosage amount than the patches that Mr. Acree wore. The test, however, is substantial similarity, not identity. The patches

that were recalled were made on the same machine, using the same process as the one used to make the patches that Mr. Acree used. And the recalls occurred at times relatively near Mr. Acree's death in January 2009; the first was in August 2008 (and is equally admissible to show notice), and the second was in August 2009. The Court concludes that these events are relevant. The Court also rejects defendants' contention that the evidence should be excluded under Rule 403. The differences between the recalled patches and Mr. Watson's may affect the weight to be given the evidence, but it has significant probative value nonetheless. The evidence, though prejudicial, is not unfairly so, and certainly not in a way that substantially outweighs its probative value. If defendants wish to propose a limiting instruction regarding the purposes for which this evidence may be considered, the Court will entertain that. Finally, it is highly unlikely that admission of this evidence will cause undue delay or jury confusion; defendants' explanation of the differences is relatively simple and is unlikely to require a significant amount of the jury's time.

The Court next considers defendants' objection to the admission of "health hazard evaluation reports" prepared as part of defendants' internal review processes. Defendants' objection that these do not concern the same lots from which Mr. Acree's patches claim and that some of them concern different dosage amounts is lacking in merit for the reasons previously discussed; the patches all have the same design and are made using the same process on the same machine. The fact that some of the reports post-date the matters at issue here likewise is not a basis to exclude them.

Defendants also argue that certain language contained in the reports is not really theirs but was required by the Food and Drug Administration. In a report dated August

5, 2009, for example, defendants listed a number of leakage incidents involving 100 mcg/h patches and describe the symptoms that some (but not all) patients experienced – such as loss of consciousness and hypoxia. A section of the report entitled "Additional Information" includes the following statement:

> The current package insert for the Fentanyl Transdermal System, issue date of August 2008, states in the BOXED WARNING section, "Using a patch that is cut, damaged, or changed in any way can expose the patient or caregiver to the contents of the patch, which can result in an overdose of fentanyl that may be fatal."

Pl.'s Resp. to Defs.' Mots. In Limine, Ex. 34 at 3. A later statement in the same report reads as follows (the reference to DSRC is to Watson's Drug Safety Review Committee):

> The DSRC has considered the leaking Fentanyl Transdermal System in batch 145287A. Exposure to leaking gel contents could result in increased absorption of fentanyl, possibly leading to signs and symptoms of opiate overdose. Alternatively, leaking gel may result in a transdermal system not containing appropriate levels of drug, possibly leading to a lack of efficacy and signs and symptoms of opiate withdrawal. Based upon the data provided to the DSRC at this time, leakage of fentanyl may lead to serious adverse events in individuals exposed to a leaking transdermal system.

Id. at 4. These statements are both made in documents authored by defendants' personnel. The latter, in particular, does not appear simply to parrot a package warning that one might attribute to regulatory authorities. But even if so, these sorts of statements are not inadmissible. They are statements made by the defendants and thus are not hearsay, and any contention that they are FDA-required statements would appear to be simple to explain. The statements are relevant and not unfairly prejudicial in a way that substantially outweighs their probative value. The Court therefore denies defendants' motion *in limine* 9.

Defendants also move to exclude evidence of adverse event reports. They argue first that they represent two-level hearsay. The first alleged level of hearsay is the report itself, typically information received from a doctor regarding an experience with a patient. Such reports would be hearsay if offered for their truth, but this evidence would be properly admissible to show notice to defendants of incidents that meet the similarity standards referenced earlier. The timing is appropriate for purposes of notice, because these matters predate the incident involving Mr. Acree. But plaintiff does not even intend to introduce adverse event reports as such. See Pl.'s Resp. to Defs.' Mots. In Limine at 25 ("But Plaintiff does not intend to introduce AERs and has not identified any on her exhibit list.") Rather, she intends to offer evidence of defendants' review and analysis of such reports – specifically, e-mails by defendants' personnel and an internal study of the adverse event reports. For this reason, the documents that defendants intend to introduce are not hearsay at all. Nor are they unfairly prejudicial in a way that substantially outweighs their significant probative value, for the reasons discussed earlier in this section. The Court therefore denies defendants' motion *in limine* 10. If defendants wish to propose a limiting instruction regarding the jury's consideration of the adverse event report information contained within the other documents, the Court will entertain such a request.

Finally, for the same reasons already discussed, the Court denies defendants' motion *in limine* 5, a catch-all category seeking to exclude evidence of other incidents. At the motion hearing, defendants argued (among other things) that because there is no evidence that Mr. Acree's patches leaked, evidence of other leaking patches is irrelevant. But although there is no direct evidence that the patches leaked – they were

discarded – that does not mean that evidence of a leak is missing. As discussed earlier and in the Court's ruling denying summary judgment, plaintiff is entitled to attempt to prove her case circumstantially, and there is circumstantial evidence that would support a finding that Mr. Acree's patch or patches leaked, causing his death.

Conclusion

The Court rules on defendants' motions *in limine* as stated in this order.

MATTHEW F. KENNELLY
United States District Judge

Date: November 23, 2012